

**CHAPTER NO. 380**

**SENATE BILL NO. 508**

**By Kilby**

**Substituted for: House Bill No. 404**

**By Sargent, Davis**

AN ACT to amend Tennessee Code Annotated, Title 4 and Title 63, to enact the Tennessee Orthotics, Prosthetics, and Pedorthics Practice Act of 2005.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 3, is amended by designating the existing sections as Part 1 and adding the following language as a new Part 2:

63-3-201. As used in this part, unless the context requires otherwise:

(1) "Board" means the board which licenses and regulates podiatrists in Tennessee under Part I of this Chapter.

(2) "Custom fabricated and fitted device" means an orthosis, prosthesis, or pedorthic device which is fabricated to original measurements or a mold for use by a patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which requires substantial clinical and technical judgment in its design and fitting.

(3) "Custom fitted device" means a prefabricated orthosis, prosthesis, or pedorthic device sized or modified for use by the patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which requires substantial clinical judgment and substantive alteration for appropriate use.

(4) "Department" means the department of health.

(5) "Director" means the director of the division of health related boards.

(6) "Commissioner" means the commissioner of health.

(7) "Division" means the division of health related boards.

(8) "Facility" means the business location where orthotic, prosthetic, or pedorthic care is provided. In the case of an orthotic/prosthetic facility, it has the appropriate clinical and laboratory space and equipment to provide comprehensive orthotic or prosthetic care and, in the case of a pedorthic facility, it has the appropriate clinical space and equipment to provide pedorthic care. Licensed orthotists, prosthetists, and pedorthists must be available to either provide care or supervise the provision of care by non-licensed staff.

(9) "Licensed orthotist" means a person licensed under this act to practice orthotics and who represents himself or herself to the public by title or description of services that includes the term "orthotic", "orthotist", "brace" or a similar title or description of services.

(10) "Licensed pedorthist" means a person licensed under this act to practice pedorthics and who represents himself or herself to the public by the title or description of services that includes the term "pedorthic", "pedorthist" or a similar title or description of services.

(11) "Licensed prosthetist" means a person licensed under this act to practice prosthetics and who represents himself or herself to the public by title or description of services that includes the term "prosthetic", "prosthetist", "artificial limb" or a similar title or description of services.

(12) "Orthosis" means a custom-designed, fabricated, fitted or modified device to correct, support or compensate for a neuro-musculoskeletal disorder or acquired condition. "Orthosis" does not include fabric or elastic supports, corsets, arch supports, low-temperature plastic splints, trusses, elastic hoses, canes, crutches, soft cervical collars, dental appliances, or other similar devices that are carried in stock and sold without modification as "over-the-counter" items by a drug store, department store, corset shop, or surgical supply facility.

(13) "Orthotic and prosthetic education program" means a course of instruction accredited by the Commission on Accreditation of Allied Health Education Programs, consisting of:

(A) An adequate curriculum of college level training and instruction in math, physics, biology, chemistry and psychology; and

(B) A specific curriculum in orthotic or prosthetic courses, including:

(i) Lectures covering pertinent anatomy, biomechanics, pathomechanics, prosthetic-orthotic components and materials, training and functional capabilities, prosthetic or orthotic performance evaluation, prescription considerations, etiology of amputations and disease processes necessitating prosthetic or orthotic use, and medical management;

(ii) Subject matter related to pediatric and geriatric problems;

(iii) Instruction in acute care techniques, such as immediate and early post-surgical prosthetics and fracture bracing techniques; and

(iv) Lectures, demonstrations, and laboratory experiences related to the entire process of measuring, casting, fitting, fabricating, aligning, and completing prostheses or orthoses.

(14) "Orthotics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing an orthosis under an order from a licensed health care practitioner authorized by law to issue such an order for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.

(15) "Orthotist" means an allied health professional who is specifically trained and educated to provide or manage the provision of a custom-designed, fabricated, modified and fitted external orthosis to an orthotic patient, based on a clinical assessment and a prescription from a health care practitioner authorized by law to write such prescriptions, to restore physiological function or cosmesis.

(16) "Over-the-counter device" means a prefabricated, mass-produced device that is prepackaged and requires no professional advice or judgment in either size selection or use, including fabric or elastic supports, corsets, generic arch supports and elastic hoses.

(17) "Off-the-shelf device" means a prefabricated prosthesis or orthosis sized or modified for use by the patient in accordance with a prescription from a health care practitioner authorized by law to write such prescriptions and which does not require substantial clinical judgment and substantive alteration for appropriate use.

(18) "Pedorthic device" means therapeutic footwear, foot orthoses for use at the ankle or below, and modified footwear made for therapeutic purposes, as prescribed by a licensed health care practitioner authorized by law to issue such prescription. "Pedorthic device" does not include non-therapeutic accommodative inlays or non-therapeutic accommodative footwear, regardless of method of manufacture, shoe modifications made for non-therapeutic purposes, unmodified, over-the-counter shoes, or prefabricated foot care products.

(19) "Pedorthic education program" means a course of instruction accredited by the Board for Certification in Pedorthics consisting of:

(A) A basic curriculum of instruction in foot-related pathology of diseases, anatomy, and biomechanics;

(B) A specific curriculum in pedorthic courses, including lectures covering shoes, foot orthoses, and shoe modifications, pedorthic components and materials, training and functional capabilities, pedorthic performance evaluation, prescription considerations, etiology of disease processes necessitating use of pedorthic devices, medical management, and subject matter related to pediatric and geriatric problems; and

(C) Lectures, demonstrations, and laboratory experiences related to the entire process of measuring and casting, fitting, fabricating, aligning, and completing pedorthic devices.

(20) "Pedorthics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing a pedorthic device under an order from a licensed health care practitioner

authorized by law to issue such order for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity.

(21) "Pedorthist" means a person who measures, designs, fabricates, fits, or services pedorthic devices and assists in the formulation of the order of pedorthic devices as ordered by a licensed health care practitioner authorized by law to issue such order for the support or correction of disabilities caused by neuro-musculoskeletal diseases, injuries, or deformities.

(22) "Person" means a natural person.

(23) "Prosthesis" means a custom designed, fabricated, fitted, or modified device to replace an absent external limb for purposes of restoring physiological function or cosmesis. "Prosthesis" does not include artificial eyes, ears, or dental appliances, cosmetic devices such as artificial breasts, eyelashes, or wigs, or other devices that do not have a significant impact on the musculoskeletal functions of the body.

(24) "Prosthetics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing a prosthesis under an order from a licensed health care practitioner authorized by law to issue such order.

(25) "Prosthetist" means an allied health professional who is specifically trained and educated to provide or manage the provision of a custom designed, fabricated, modified, and fitted external limb prosthesis to a prosthetic patient, based on a clinical assessment and a prescription from a health care practitioner authorized to write such prescriptions, to restore physiological function or cosmesis.

(26) "Prosthetist/Orthotist" means a person who practices both disciplines of prosthetics and orthotics and who represents himself or herself to the public by title or by description of services.

(27) "Resident" means a person who has completed an education program in either orthotics or prosthetics and is continuing such person's clinical education in a residency program approved by the board.

63-3-202.

(a) The board shall adopt rules and regulations, promulgated in compliance with all requirements of the Uniform Administrative Procedures Act compiled in Title 4, Chapter 5, to:

(1) Establish licensure categories and issue licenses for prosthetists, orthotists and pedorthists;

(2) Establish the qualifications, educational courses, curriculum, hours, and standards which are prerequisite to issuance of all levels and types of licensure established pursuant to subsection (1); provided, however, such qualifications shall include the following:

(A) To qualify for a license to practice orthotics or prosthetics, a person shall:

(i) Possess a baccalaureate degree or equivalent semester hours to four (4) years of study at a four-year college or university;

(ii) Complete the amount of formal training, including but not limited to any necessary hours of classroom education and clinical practice required by the board;

(iii) Complete a clinical residency in the professional area for which a license is sought in accordance with standards, guidelines, or procedures for residencies inside or outside this state established and approved by the board. The majority of training must be devoted to services performed under the supervision of a licensed practitioner of orthotics or prosthetics or a person who has obtained certification from the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification;

(iv) Pass all written, practical, and oral examinations that are required and approved by the board; and

(v) Be qualified to practice in accordance with commonly accepted standards of orthotic and prosthetic care acceptable to the board.

(B) To qualify for a license to practice pedorthics, a person shall:

(i) Possess a high school diploma or comparable credential approved by the board;

(ii) Complete the amount of formal training, including but not limited to any necessary hours of classroom education and clinical practice required by the board;

(iii) Pass all examinations that are required and approved by the board;

(iv) Complete a qualified work experience program or internship in pedorthics in accordance with standards and procedures established by the board; and

(v) Be qualified to practice in accordance with commonly accepted standards of pedorthic care acceptable to the board.

(C) A person may be licensed in more than one discipline.

(3) Establish the circumstances or conditions, if any, under which persons shall be entitled to exemption from licensure during training, while waiting to take

or receive the results of any required examination, and/or upon meeting specified minimum educational and clinical qualifications;

(4) Select the examination or examinations to be utilized as the board's licensure examination or examinations and the prerequisites, if any, for admission to the examination or examinations. The board is authorized to enter into a contract or agreement with the chosen examination service or services or select an intermediary between the board and the examination service or services to process applicants for the examination or examinations;

(5) Establish any other criteria for issuance of licensure, which are reasonably related to the safe and competent performance of prosthetics, orthotics and pedorthics;

(6) Accredite continuing education courses;

(7) Establish the fees to be paid, for each of the following:

(A) Application for licensure;

(B) Renewal or reinstatement of licensure;

(C) Late renewal of licensure;

(D) Application for continuing education course accreditation; and

(E) Duplicate or replacement license.

The fees shall be set at a level which is adequate to pay all the expenses of implementing and administering this part. All deposits and disbursements shall be handled in accordance with § 63-1-137.

(8) Establish the continuing education requirements for license holders which shall include the frequency of reporting, number of hours, types of courses, approval of courses, methods of proving compliance, penalties for violation and all fees necessary for implementation of the continuing education process;

(9) Regulate the nature, manner, content and extent of advertising by persons licensed under this part; and

(10) Delineate the actions relative to therapeutic footwear and medical devices for the foot and ankle which must be performed by licensed health care practitioners.

(b) The board shall have the authority to:

(1) Conduct disciplinary hearings in accordance with the Uniform Administrative Procedures Act compiled in Title 4, Chapter 5; and

(2) Issue advisory private letter rulings to any affected person licensed under this part who makes such a request regarding any matters within the

board's primary jurisdiction. Such private letter ruling shall affect only the person making such inquiry and shall have no precedential value for any other inquiry or future contested case that might come before the board. Any dispute regarding a private letter ruling may, if the board chooses to do so, be resolved pursuant to the declaratory order provisions of § 4-5-223.

63-3-203.

(a) Licenses shall be issued and renewed by the board pursuant to the division's biennial issuance and renewal system.

(b) Any person who has been issued a license to practice under this part and who wishes to retire that license shall file with the board an affidavit on a form to be furnished by the board, stating the date on which the person retired from such practice and such other facts as shall tend to verify such retirement as the board deems necessary. Any such person who thereafter wishes to reenter practice must request reinstatement of licensure.

(c) Any license issued by the board shall contain the name of the person to whom it is issued, the address of the person, the date and number of the license and such other information as the board deems necessary. The address contained on the license shall be the address where all correspondence and renewal forms from the board shall be sent. Any person whose address changes shall, within thirty (30) days thereafter, notify the board of the address change. The most recent address contained in the board's records for each license holder shall be the address deemed sufficient for purposes of service of process.

(d) Every person issued a license pursuant to this chapter shall either keep such license prominently displayed in the office or place in which such person practices or have it stored in a place from which it can be immediately produced upon request of a patient or a representative of the department.

(e) Any person whose license has been lost or destroyed may make application to the board for a replacement. Such application shall be accompanied by an affidavit setting out the facts concerning the loss or destruction of the original license.

(f) Any person whose name is changed by marriage or court order may surrender his or her license and apply to the board for a replacement license.

63-3-204.

(a) The board shall have the power to:

(1) Deny, restrict or condition a license;

(2) Permanently or temporarily withhold issuance of a license;

(3) Suspend, limit or restrict a previously issued license for such time and in such manner as the board may determine;

(4) Reprimand, suspend, revoke or take such other disciplinary action in relation to an applicant or license holder as the board in its discretion may deem proper; or

(5) Permanently revoke a license.

(b) The grounds upon which the board shall exercise such power include, but are not limited to, circumstances wherein the person:

(1) Is guilty of fraud or deceit in the procurement or holding of the license;

(2) Has been convicted of a felony in a court of competent jurisdiction, either within or outside of this state, unless the conviction has been reversed and the holder of the license discharged or acquitted, or if the holder has been pardoned with full restoration of civil rights, in which case the license shall be restored;

(3) Is or has been afflicted with any medical problem, disability, or addiction, which, in the opinion of the board, would impair professional competence;

(4) Has knowingly aided and abetted a person who is not a license holder, or is not otherwise authorized pursuant to this chapter, to perform the duties of a license holder under this chapter;

(5) Has undertaken or engaged in any practice beyond the scope of duties permitted a license holder under this chapter;

(6) Has impersonated a license holder or former license holder or is under an assumed name performing the duties authorized to be performed only by a licensed person;

(7) Has been found guilty of violations of a code of ethics which the board shall establish by regulation;

(8) Is or has been found guilty of incompetence or negligence in his or her performance as a license holder;

(9) Acts in a manner unprofessional, dishonorable or unethical or has been found guilty of unprofessional, dishonorable or unethical conduct;

(10) Violates or attempts to violate, directly or indirectly, or assists or aids in the violation of, or conspires to violate, any provision of this chapter or any lawful order of the board issued pursuant thereto, or any of the rules or regulations promulgated pursuant thereto, or any criminal statute of the state;

(11) Is habitually intoxicated or engages in personal misuse of any drugs or the use of intoxicating liquors, narcotics, controlled substances or other drugs or stimulants in such manner as to adversely affect the person's ability to practice; or

(12) Has received disciplinary action from another state or territory of the United States that has licensed or certified the person to practice in that state for any acts or omissions which would constitute grounds for discipline of a person licensed in this state. A certified copy of the initial or final order or other equivalent document memorializing the disciplinary action from the disciplining state or territory shall constitute prima facie evidence of violation of this section and be sufficient grounds upon which to deny, restrict or condition licensure or renewal or discipline a person licensed in this state.

63-3-205.

(a) On and after January 1, 2008, no person shall practice orthotics, prosthetics, or pedorthics in this state, or hold himself or herself out as being able to practice either profession, or dispense an orthosis, prosthesis, or pedorthic device, unless such person is licensed in accordance with the requirements of this chapter.

(b) Until January 1, 2008, a person certified by the American Board for Certification in Orthotics and Prosthetics, Inc., with the title of Certified Orthotist (CO), Certified Prosthetist (CP), or Certified Orthotist-Prosthetist (CPO) or The Board for Orthotist/Prosthetist Certification with the title of Board of Orthotic Certification - Orthotist (BOCO) or Board of Certification - Prosthetist (BOCP) or holding similar certifications from other accrediting bodies with equivalent educational requirements and examination standards may apply for and may be granted orthotic or prosthetic licensure under this act upon payment of the required fee. After that date, any applicant for initial licensure as an orthotist or a prosthetist shall meet the requirements of this part regarding license.

(c) Until January 1, 2008, a person certified as a Certified Pedorthist (CPED) by the Board of Certification in Pedorthics, Incorporated, or a person certified as a CO, CP or CPO by the American Board for Certification in Orthotics and Prosthetics, Inc. or certified as a BOCO or BOCP by the Board for Orthotist/Prosthetist Certification or holding similar certifications from other accrediting bodies with equivalent educational requirements and examination standards may apply for and may be granted pedorthic licensure under this act upon payment of the required fee. After that date, any applicant for initial licensure as a pedorthist shall meet the requirements of this part regarding licensure.

(d) Notwithstanding any other provision of this chapter to the contrary, a person who has practiced full-time for a minimum of the past five (5) years in a prosthetic/orthotic facility as an orthotist or prosthetist or in a pedorthic facility as a pedorthist may file an application with the board before January 1, 2007, in order to continue to practice orthotics, prosthetics, or pedorthics and may be issued a license to practice orthotics, prosthetics, or pedorthics under the provisions of this act without examination upon receipt by the division of payment of the licensing fee required and after the board has completed an investigation of the applicant's work history. The investigation may include, but is not limited to, completion by the applicant of a questionnaire regarding the applicant's work history and scope of practice.

63-3-206. A licensed orthotist, prosthetist or pedorthist may provide care or services only if the care or services are provided pursuant to an order from a licensed health care practitioner authorized to issue such an order.

63-3-207.

(a) The scope of practice of a licensed orthotist, prosthetist, or pedorthist shall not include the right to diagnose a medical problem or condition or the right to give medical advice as to the nature, cause, or treatment for the problem or condition for which the orthotist, prosthetist, or pedorthist device is being dispensed. However, the scope of practice of a licensed orthotist, prosthetist, or pedorthist does include the right to provide information or demonstration regarding the proper use and care of the device and to make adjustments to the device as needed.

(b) No person shall dispense or sell an over-the-counter device or an off-the-shelf device based upon an image of the customer's limb captured by the person through a mold, cast, scanning device, digital appliance, or pressure sensitive device, unless the customer has first presented to that person a written prescription for that device from a health care practitioner authorized by law to write such a prescription.

63-3-208.

(a) Nothing in this act, or in the rules adopted by the board pursuant to this act, shall be interpreted to limit or restrict a health care practitioner licensed under Title 63 from engaging in the full scope of practice of such person's profession, training or services. Nothing in this act, or in the rules adopted by the board pursuant to this act, shall be interpreted or permitted to limit or restrict individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted device, including but not limited to over-the-counter devices or off-the-shelf devices, so long as such individual does not create a cast, mold or scan of a part of the human body for the purpose of constructing a medical device to treat a patient's medical condition and so long as such individual meets one of the following criteria for such device:

(1) Documented training from a manufacturer; or training from a licensed or certified orthotist, prosthetist, or pedorthist; or

(2) Certification or registration as a fitter of orthotics, prosthetics, or pedorthics, from a nationally recognized board or association such as the Board for Orthotist/Prosthetist Certification (BOC), the Board of Certification for Pedorthists, the National Community Pharmacists Association (NCPA), or the American Board for Certification in Orthotics and Prosthetics (ABC); or

(3) Direct supervision by a trained and experienced, or certified, or registered, fitter of orthotic, prosthetic, or pedorthic devices.

(b) Nothing in this act, or in the rules adopted by the board pursuant to this act, shall be interpreted or permitted to limit or restrict individuals acting under the supervision and control of a pharmacist or pharmacy licensed under Title 63, or home medical equipment provider licensed under Title 68, from measuring, fitting or adjusting any non-custom fabricated and fitted pedorthic devices, including but not limited to diabetic shoes, so long as such individual meets the criteria of either subdivision (a)(2) or (3) and so long as the individual does not create a cast, mold or scan of a part of the

human body for the purpose of constructing a medical device to treat a patient's medical problem.

Section 63-3-209. Nothing in this part shall be construed to restrict:

(1) The practice of orthotics, prosthetics, or pedorthics by a person who is employed by the federal government or any bureau, division, or agency of the federal government while in the discharge of the employee's official duties;

(2) The practice of orthotics, prosthetics, or pedorthics by:

(A) A student enrolled in a school of orthotics, prosthetics, or pedorthics;

(B) A resident continuing such resident's clinical education in a residency accredited by the National Commission on Orthotic and Prosthetic Education; or

(C) A student in a qualified work experience program or internship in pedorthics; or

(3) The measuring, fitting or adjusting of an orthotic device by an employee or authorized representative of an orthosis manufacturer registered with the federal Food and Drug Administration, when such employee or representative is supervised by a licensed health care professional authorized by law to prescribe, measure or fit such device and the measuring, fitting or adjusting of such device occurs in the office of such licensed health care professional or in a health care facility.

63-3-210.

(a) Any person who practices in this state without having first complied with the provisions of this part commits a Class C misdemeanor; provided, however, for a period of one (1) year after the effective date of this part an offense under this section shall only result in a warning and such person shall have thirty (30) days to comply with the provisions of this part.

(b) The board of registration in podiatry shall inform persons to be regulated by the provisions of this part of the regulations to be imposed by this part.

63-3-211.

(a) The board shall have the authority to petition any circuit or chancery court having jurisdiction over any person who is practicing without a license, or to whom a license has been denied, or whose license has been suspended or revoked by action of the board, to enjoin such person from continuing to practice within this state.

(b) Jurisdiction is conferred upon the circuit and chancery courts of this state to hear and determine all such causes and to exercise full and complete jurisdiction in such injunctive proceedings.

63-3-212.

(a) The board may utilize one or more screening panels in its investigative and disciplinary process to assure that complaints filed and investigations conducted are meritorious and to act as a mechanism for resolution of complaints and/or diversion to professional peer review organizations and/or impaired professionals' associations or foundations of those cases which the board, through established guidelines, deems appropriate.

(b) The screening panel has the authority to administer oaths to witnesses.

(c) Members of a screening panel may be drawn from the membership of the board or may be appointed by the board. Non-board members shall meet the requirements of membership on the board and may include a consumer member. A board member serving on a panel shall not participate in a contested case involving any matter heard by the panel.

63-3-213.

(a) To assist in the implementation and administration of this part, the governor shall initially appoint to the board one (1) person who is eligible for licensure as an orthotist, or prosthetist, or pedorthist.

(b) That person's term of office on the board shall be three (3) years. Upon expiration of that person's term, the governor shall appoint a person licensed under this part to fill this position on the board.

(c) A person may serve more than one term in this position on the board.

(d) The governor may remove this member of the board from office for neglect of duties, malfeasance in office, incompetence or professional misconduct.

(e) The governor may fill a vacancy in this position upon the member's resignation or death.

(f) In making appointments to this position on the board, the governor shall consider persons recommended by the professional organization of orthotists, prosthetists, and pedorthists in Tennessee.

(g) The person filling this position on the board shall receive the same per diem and reimbursement for travel and other necessary expenses which is received by other members of the board.

(h) The person filling this position shall have the right to vote on all matters considered by the board.

SECTION 2. This act shall take effect, for purposes of making an appointment to the board and for promulgation of rules, upon becoming a law. For all other purposes, this act shall take effect on January 1, 2006, the public welfare requiring it.

PASSED: May 24, 2005

  
JOHN S. WILDER  
SPEAKER OF THE SENATE

  
JIMMY NAIFEH, SPEAKER  
HOUSE OF REPRESENTATIVES

APPROVED this 9<sup>th</sup> day of June 2005

  
PHIL BREDESEN, GOVERNOR